K100192 FEB - 4 2010

019

Saeshin Precision Co., Ltd.
#93-15, Paho-Dong, Dalseo-Gu, Daegu, 704-220, Republic of Korea
Tel 82 53-587-2345 Fax 82 53-587-2347

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: November 30, 2009

1. Company and Correspondent making the submission:

	Company
Name	Saeshin Precision Co., Ltd.
Address	#93-15, Paho-dong, Dalseo-Gu, Daegu, 704-220, Republic of Korea
Phone	+82 53-587-2345
Fax	+82 53-587-2347
Contact	Y. S. Lee

2. Device:
   Proprietary Name – STRONG Dental Handpieces
   Common Name – Dental Handpieces and Accessories
   Classification Name – Handpiece, Contra- And Right-Angle Attachment, Dental

3. Predicate Device:
   - Surgical Contra-Angle Handpieces Types WS-56E, Surgical straight Handpieces Types, S-11, K011061
   - STRONG Implant Handpieces, K092412

4. Classifications Names & Citations:
   EGS, 872.4200

5. Description:
   The STRONG Dental Handpieces; AT-II, ACL-01C, ACL(B)-01C and ACL-02C is gear driven hand-held dental handpieces with transmission ratio of 1:1. It can be driven by torque adjustable electrical motors for surgery treatment. It is attached to drive via ISO 3964 coupling. The head clamp accepts instrument complying with ISO 1797-1. It has contra-angle(AT-II has straight-angle) attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

SAESHIN
Saeshin Precision Co., Ltd.
#93-15, Paho-Dong, Dalseo-Gu, Daegu, 704-220, Republic of Korea
Tel 82 53-587-2345 Fax 82 53-587-2347

6. Indication for use:

The STRONG Dental Handpieces is indicated for wide range of dental procedures.

- AT- II for the application in the area of the front teeth, root tip resection, bone removal, osteotomia on the upper and lower jaw, preprosthetic surgical modellation, sequestrotomia, fenestration on the alveolar appendix, apical ventilation, bone modellation, bone smoothing.
- ACL-01, ACL(B)-01C and ACL-02C for the osteotomia on the upper and lower jaw, germectomia, sequestrotomia.

7. Review:

The STRONG Dental Handpieces has the same device characteristics as the predicate device, the Surgical Contra-Angle handpieces Types WS-56E, Surgical Straight Handpieces Types S-11; intended use, material, design and use concept are similar. And they also comply to ISO 3964 coupling and ISO 1797-1 shank.

Based on the comparison of intended use and technical features, the STRONG Dental Handpieces are substantially equivalent to the predicate devices.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Saeshin Precision Co., Ltd. concludes that the STRONG Dental Handpieces is safe and effective and substantially equivalent to predicate devices as described herein.

9. Saeshin Precision Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 4 2010

Saeshin Precision Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
Laboratory and Testing
2600 Northwest Lake Road
Camas, Washington 98607-9526

Re: K100192
Trade/Device Name: STRONG Dental Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Acessories
Regulatory Class: I
Product Code: EGS
Dated: January 4, 2010
Received: January 22, 2010

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K K100192

Device Name: STRONG Dental Handpieces

Indication for use:

The STRONG Dental Handpieces is indicated for wide range of dental procedures.

- AT- II for the application in the area of the front teeth, root tip resection, bone removal, osteotomia on the upper and lower jaw, preprosthetic surgical modellation, sequestrotomia, fenestration on the alveolar appendix, apical ventilation, bone modellation, bone smoothing.
- ACL-01, ACL(B)-01C and ACL-02C for the osteotomia on the upper and lower jaw, germectomia, sequestrotomia.

Prescription Use ✓ (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____ (Per 21CFR801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr. K. P. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100192